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April 14, 2009

Reference: Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages; Federal Dockets Management System Docket FDA-2009-D-0001

Dear Sir/Madam,

PDA is pleased to offer comments on the FDA Draft Guidance for Industry on *Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages*. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in supply chain issues including members representing our Regulatory Affairs and Quality Committee. PDA wishes to thank the FDA for the opportunity to offer comments on this Draft Guidance.

PDA endorses the need to develop standards and identify and validate effective technologies to secure the drug supply chain against counterfeit and diverted drug products, as well as drug products which fail to meet their quality requirements and standards. The draft guidance recommends use of a Standardized Numerical Identifier (SNI) as part of the system to identify, validate, authenticate and track and trace prescription drugs. The guidance also recommends that, to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier. The guidance recommends use of the product National Drug Code (NDC) number followed by a serialized number. **PDA recommends that FDA adopt the GS1 Standard instead and not recommend the use of the NDC and SNI.** Many companies have already adopted this standard. GS1 is a recognized standard setter and is in fact referenced by the FDA in the document. It is therefore unclear why the agency is proposing an alternative method of identifying product to that recognized in the GS1 standard.

Again, PDA appreciates the opportunity to comment on this draft guidance document and provides this recommendation for your consideration. PDA believes that our comments will clarify and strengthen the guidance document to better serve the needs of both regulators and industry.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Robert B. Myers
President, PDA

H: dana/RAQC/Standards for Securing the Drug Supply Chain Comment Letter
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